

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:
75-547

MICROBIOLOGY REVIEW

OFFICE OF GENERIC DRUGS, HFD-620
Microbiology Review #2
February 21, 2001

A. 1. ANDA 75-547

APPLICANT: Bedford Laboratories
270 Northfield Road
Bedford, OH 44146

2. PRODUCT NAME: Thiotepa for Injection

3. DOSAGE FORM AND ROUTE OF ADMINISTRATION: 15mg/vial,
Lyophilized; I/V, Intracavitary, Intravesicle

4. METHOD(S) OF STERILIZATION:

5. PHARMACOLOGICAL CATEGORY: Anti-Neoplastic

B. 1. DATE OF INITIAL SUBMISSION: December 29, 1998

2. DATE OF AMENDMENT: February 2, 2001
Subject of this Review (Received February 5, 2001)

3. RELATED DOCUMENTS: None

4. ASSIGNED FOR REVIEW: February 21, 2001

C. REMARKS: The subject amendment provides for the response to microbiology deficiencies in the correspondence dated April 21, 2000.

D. CONCLUSIONS: The submission is **recommended** for approval on the basis of sterility assurance. Specific comments are provided in "E. Review Notes".

Nrapendra Nath, Ph.D.

cc:

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Micro Rev. 2

2/21/01

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OFFICE OF GENERIC DRUGS, HFD-620
Microbiology Review #1
April 17, 2000

A. 1. ANDA 75-547

APPLICANT: Bedford Laboratories
270 Northfield Road
Bedford, OH 44146

2. PRODUCT NAME: Thiotepa for Injection

3. DOSAGE FORM AND ROUTE OF ADMINISTRATION: 15mg/vial,
Lyophilized; I/V, Intracavitary, Intravesicle

4. METHOD(S) OF STERILIZATION:

5. PHARMACOLOGICAL CATEGORY: Anti-Neoplastic

B. 1. DATE OF INITIAL SUBMISSION: December 29, 1998
Subject of this Review (Received December 31, 1998)

2. DATE OF AMENDMENT: ~~July 20, 1999~~ None
Subject of this Review (Received ~~July 22, 1999~~)

3. RELATED DOCUMENTS: None

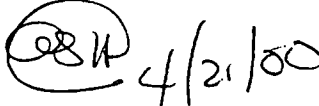
4. ASSIGNED FOR REVIEW: April 11, 2000

C. REMARKS: The subject drug product was manufactured by Ben Venue Laboratories' manufacturing facility in Bedford, OH in the Aseptic Suites #11, 13, 111 and 112. Amendment dated July 20, 1999 was reviewed for its Microbiology content.

D. CONCLUSIONS: The submission is not recommended for approval on the basis of sterility assurance. Specific comments are provided in "E. Review Notes" and "Microbiology Comments to be Provided to the Applicant" found at the end of this review. The deficiencies represent a minor amendment.

 4/21/00
Nrapendra Nath, Ph.D.

cc:

 4/21/00

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Micro Rev. 1
4/21/00